Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 9, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.705, amend table 1 to paragraph (a) by adding in alphabetical order the entries ''Banana'' and ''Coffee, green bean'' to read as follows:

§ 180.705 Mefentrifluconazole; tolerances for residues.

(a) * * *

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
* * * * *	
Banana [1]	1.5
* * * * *	
Coffee, green bean [1]	0.4
* * * * *	

[1] There are no U.S. registrations as of December 15, 2021.

* * * * *

[FR Doc. 2021–27093 Filed 12–14–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2020–0421; FRL–9282–01–OCSPP]

Pyflubumide; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyflubumide in or on tea, dried and tea, instant. Nichino America, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 15, 2021. Objections and requests for hearings must be received on or before February 14, 2022, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2020–0421, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2020–0421 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before February 14, 2022. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2020–0421, by one of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/contacts.html*. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of April 22, 2021 (86 FR 21317) (FRL–10022–59), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0E8829) by Nichino America, Inc. 4550 Linden Hill Road, Suite 501, Wilmington, DE 19808. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide pyflubumide, including its metabolites and degradates, in or on the raw agricultural commodity tea, dried at 70 parts per million (ppm). That document referenced a summary of the petition prepared by Nichino America, Inc., the registrant, which is available in the docket, *https://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is establishing the tolerance for tea, dried at a different level than requested and is also establishing a tolerance for tea, instant. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Neither of these exposures are relevant to this action, however. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for pyflubumide. EPA's assessment of exposures and risks associated with pyflubumide follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The toxicological database for pyflubumide is complete for the establishment of a tolerance without U.S. registration. Based on a weight-of-evidence approach and considering all available pyflubumide hazard and exposure information, EPA waived the requirement for a subchronic neurotoxicity (SCN) study, an immunotoxicity study, and a comparative thyroid assay (CTA). The affected target organs following the administration of pyflubumide included the thyroid (rat, mouse, and dog), liver (rat, mouse, rabbit, and dog), kidney (rat and dog), adrenal gland (mouse, rat, and dog), heart (rat and dog), and lung (developing rat).

No evidence of increased qualitative or quantitative susceptibility was seen in the rat and rabbit developmental toxicity studies. Increased quantitative susceptibility was observed in the multigeneration reproduction toxicity study where lung lesions in offspring were observed at a lower dose (6 mg/kg/day) than the dose eliciting parental toxicity (29 mg/kg/day).

There was no evidence of neurotoxicity in the available acute neurotoxicity (ACN) study or throughout the database (subchronic, chronic, and mechanistic studies). The chronic point of departure (POD) (1 mg/kg/day) is protective of effects seen in the multigeneration reproduction toxicity study.

For the acute dietary exposure scenario (females of childbearing age and infants), the point of departure (POD) is based on the increased incidence of lung lesions (alveolar dilatation) from dosing on two consecutive days (post-natal day (PND) 4–5 or PND 6–7) in a mechanistic study that evaluated the occurrence of alveolar dilatation in rat pups by short term oral administration of pyflubumide. Since these lung effects resulted from at most two exposures, this finding was selected to be protective of potential acute lung effects that could occur due to a single day's exposure to pyflubumide during the perinatal period. The increased incidence of lung lesions was observed in rat pups and was not found in maternal rats. Nursing pups may be exposed through the mother's milk which can result in the observed lung effects.

The POD selected for chronic dietary is based on bile duct hyperplasia and decreased triglycerides in both sexes; increased liver weights in females; increased urinary protein, urine volume, increased incidence of kidney urinary casts; and increased incidence of tubular basophilic change in the kidney in males in a one-year chronic rat toxicity study. This POD is protective of all adverse effects observed in the multigeneration reproductive, the chronic dog, the rat carcinogenicity, and the mouse carcinogenicity studies. It is also protective of lung effects observed across studies.

Pyflubumide is classified as: ''Suggestive Evidence of Carcinogenic Potential'' based on treatment-related hepatocellular adenomas in male mice at a dose level of 176 mg/kg/day. There is no mutagenic concern for pyflubumide. The quantification of risk using a non-linear approach (*i.e.,* a chronic population adjusted dose) will adequately account for all chronic toxicity, including potential carcinogenicity, that could result from exposure to pyflubumide.

Specific information on the studies received and the nature of the adverse effects caused by pyflubumide as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *https://www.regulations.gov* in document ''Pyflubumide. Human Health Risk Assessment for a Petition for the Establishment of Permanent Tolerances for Residues on Tea without a U.S. Registration. New Active Ingredient.'' hereinafter ''Pyflubumide Human Health Risk Assessment'' at pages 24–67 in docket ID number EPA–HQ–OPP–2020–0421.

B. Toxicological Points of Departure/ Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/ safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *https://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticide*.

A summary of the toxicological endpoints for pyflubumide used for human risk assessment can be found in the Pyflubumide Human Health Risk Assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to pyflubumide, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from pyflubumide in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for pyflubumide for only infants (<1 year old). Although no adverse effects were observed for females of childbearing age (13 to 49 years old), risk estimates for females of childbearing age (13 to 49 years old) are provided since there is still the potential for nursing infants to be exposed to pyflubumide from breast milk of mothers who consume treated tea. Thus, the risk estimate for females of childbearing age (13 to 49 years old) is protective for nursing infants. No acute dietary analysis was performed for the general population because an appropriate acute toxicological endpoint was not identified for the general population. In estimating acute dietary exposure, EPA used 2003–2008 food consumption data from the United States Department of Agriculture (USDA), National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA used the Maximum Residue Limit (MRL) calculator to estimate the upper bound limit for combined residues of pyflubumide (parent) and pyflubumide-NH (metabolite) with 100 percent crop treated (PCT) assumptions.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used 2003–2008 food consumption data from the USDA NHANES/WWEIA. As to residue levels in food, EPA used the MRL calculator to estimate the upper bound limit for combined residues of pyflubumide and pyflubumide-NH with 100 PCT assumptions.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Based on the data discussed in Unit III.A., EPA has concluded that a chronic reference dose (cRfD) and chronic population-adjusted dose (cPAD) are protective for all chronic toxicity, including any potential carcinogenicity. Thus, a separate quantitative cancer dietary exposure assessment was not conducted.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for pyflubumide. An estimated upper bound limit based on the combined residue levels of pyflubumide and pyflubumide-NH at a 7-day preharvest interval, and 100 PCT, were assumed for all food commodities.

2. *Dietary exposure from drinking water.* EPA assumes that there is no exposure through drinking water because pyflubumide is not registered for use in the United States. Because residues are not expected in drinking water, dietary risk estimates include exposures from food only.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Pyflubumide is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency considers ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to pyflubumide and any other substances. In addition, pyflubumide does not appear to produce a toxic metabolite that is produced by other substances. For the purposes of this action, therefore, EPA has not assumed that pyflubumide has a common mechanism of toxicity with other substances.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects. The margin of safety accounts for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines, based on reliable data, that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* No evidence of increased qualitative or quantitative susceptibility was seen in the rat and rabbit developmental toxicity studies. However, increased quantitative susceptibility was observed in the offspring of the multigeneration reproduction toxicity study where lung lesions in offspring were observed at a lower dose than the dose eliciting parental toxicity. A mechanistic study found that the increased incidence of lung lesions (alveolar dilatation and hemorrhage), following exposure to pyflubumide, was observed during post-natal exposure without any effects seen during *in utero* exposure. Although

quantitative susceptibility was observed in the multigeneration reproduction study at 6 mg/kg/day, a clear level at which no adverse effects occurred was identified at 1 mg/kg/day. In two mechanistic studies where lung lesions were identified, a clear NOAEL was established. Oral gavage administration of the parent compound (pyflubumide) to rat pups led to the increased incidence of lung lesions at a lower dose (10 mg/kg/day) than the metabolites (50 mg/kg/day) and a clear NOAEL was established at 2 mg/kg/day. In addition, oral gavage administration of the parent (50 mg/kg/day) over a two-day period (post-natal day [PND] 4–5 or PND 6–7), led to the increased incidence of lung (alveolar enlargement) lesions in the pups and a clear NOAEL was established at 10 mg/kg/day. An acute exposure below 10 mg/kg/day is not likely to result in the development of lung lesions. A point of departure was established for both the acute (10 mg/kg/day) and chronic dietary (1 mg/kg/day) exposure scenario which is protective of lung effects observed in the aforementioned studies. The combination of these factors provided a weight of the evidence to support reducing the FQPA safety factor to 1X.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for pyflubumide is complete for evaluating and characterizing toxicity, assessing offspring susceptibility under FQPA, and selecting endpoints for the exposure pathways of concern. The developmental toxicity studies in rats and rabbits, a multigeneration reproduction toxicity study, an acute neurotoxicity study in rats, and mechanistic studies on the incidence of lung lesions in rat pups are available for FQPA consideration.

ii. There is no indication that pyflubumide is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional uncertainty factors to account for neurotoxicity.

iii. As stated above, no evidence of increased qualitative or quantitative susceptibility was seen in the rat and rabbit developmental toxicity studies. However, increased quantitative susceptibility was observed in the offspring of the multigeneration reproduction toxicity study where lung lesions in offspring were observed at a lower dose than the dose eliciting parental toxicity. The concern for the susceptibility observed in the multigeneration reproductive toxicity study is low, as there is a clear NOAEL established for the offspring effects and the PODs selected for risk assessment are protective of the observed susceptibility.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% PCT and combined residue levels for pyflubumide and pyflubumide-NH at a 7-day preharvest interval. These assessments will not underestimate the exposure and risks posed by pyflubumide.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions described in this unit for acute exposure, EPA has concluded that acute exposure to pyflubumide from food only will utilize 3.5% of the aPAD for females (13 to 49 years old). The acute dietary risk estimate for females (13 to 49 years old) is protective for nursing infants because lactating mothers who consume tea with pyflubumide residues are not expected to have lower exposures than infants who subsequently consume the mother's breast milk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to pyflubumide from food only will utilize 7.7% of the cPAD for adults (50 to 99 years old), the most highly exposed population subgroup. There are no residential uses for pyflubumide.

3. *Short and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because pyflubumide is not registered in the United States, the only exposures will be dietary, from residues in or on imported tea; therefore, no short-term or intermediate-term residential exposure is expected. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for pyflubumide.

4. *Aggregate cancer risk for U.S. population.* As stated in Unit III.A, EPA has concluded that the chronic reference dose (cRfD) will adequately account for all repeated exposure/chronic toxicity, including carcinogenicity, which could result from exposure to pyflubumide. Based on the lack of chronic risk at regulated levels of exposure, EPA concludes that exposure to pyflubumide will not pose an aggregate cancer risk.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to pyflubumide residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (QuEChERS-based high-performance liquid chromatography method with tandem mass spectrometry detection (LC/MS/MS), Method A) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

The Codex has not yet established a MRL for pyflubumide residues in or on tea, dried or tea, instant. The Joint Food and Agriculture Organization (FAO)/World Health Organization (WHO) Meeting on Pesticide Residues (JMPR)

evaluated toxicology and residue data for apple and tea submitted by Nichino in September 2019. JMPR proposed an MRL level of 80 ppm for tea, dried (Pesticide Residues in Food 2019—Joint FAO/WHO Meeting on Pesticide Residues, pg 1620–1622; *https://www.fao.org/3/ca7455en/ca7455en.pdf*). The U.S. tolerance of 80 ppm for residues of pyflubumide in/on tea, dried is harmonized with the MRL proposed by JMPR.

C. Revisions to Petitioned-For Tolerances

The petition requested tolerances for residues of pyflubumide in or on tea, dried at 70 ppm. EPA is establishing the tolerance for residues of pyflubumide in or on tea, dried at 80 ppm. Two of the submitted field residue trials were conducted at half the label rate. EPA normalized those resulting residues to a 1X rate using proportionality and used the Organization for Economic Co-operation and Development (OECD) MRL calculation procedures, which resulted in a tolerance level of 80 ppm for tea, dried. EPA is also establishing a tolerance for tea, instant, which is another processed commodity of tea, plucked leaves, and EPA has determined that the same tolerance of 80 ppm is appropriate for instant tea.

V. Conclusion

Therefore, tolerances are established for residues of pyflubumide, including its metabolites and degradates, in or on tea, dried at 80 ppm and tea, instant at 80 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 9, 2021.

Edward Messina,

Director, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Add § 180.722 to subpart C to read as follows:

§ 180.722 Pyflubumide; tolerances for residues.

(a) *General.* Tolerances are established for residues of pyflubumide, including its metabolites and degradates, in or on the commodities in Table 1 to this paragraph (a). Compliance with the tolerance levels specified in Table 1 to this paragraph (a) is to be determined by measuring residues of pyflubumide (1,3,5-trimethyl-*N*-(2-methyl-1-oxopropyl)-*N*-[3-(2-methylpropyl)-4-[2,2,2-trifluoro-1-methoxy-1-(trifluoromethyl)ethyl]phenyl]-1*H*-pyrazole-4-carboxamide) in or on the following commodities:

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
Tea, dried	80
Tea, instant	80

(b)–(d) [Reserved].

[FR Doc. 2021–27147 Filed 12–14–21; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 217

[Docket No. 211208–0254]

RIN 0648–BK69

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to U.S. Navy Construction at Naval Station Newport in Newport, Rhode Island

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and